

Noridians' Responses to Provider Recommendations for LCD Circulating Tumor Cell Marker Assays:

Comment: One provider supported use of CTC assay for a specific oncological situations. This oncologist also noted the rarity of any of the situations and his use of the assay on only one occasion since its development in a very busy practice. The commenter suggested some process for claim specific determinations be made.

Response: Noridian and CMS recognize that exceptions are always possible and will review claims' documentation at the redeterminations level (first level of appeals). An independent payment decision will be made at that level.

Comment: Many oncologists and two Oncology Societies recommended against coverage of the CTC assay, indicating its lack of utility.

Response: Noridian agrees with the providers. The literature does not demonstrate necessity of the test. "The CTC Assay produces prognostic information that is not validated as actionable." - Provider group. Medicare may not reimburse the costs of services which do not or should not alter patient management.

Comment: Commenter noted utility of test for screening and "rule out" purposes.

Response: Medicare is statutorily excluded from reimbursement of screening tests, except as specifically named in the Law. "Ruling out" any condition with any test in the absence of signs or symptoms of a diseases is similarly statutorily excluded. Moreover, the test hadn't been shown to be medically reasonable or necessary for this purpose.

Comment: Many Oncologists reported the assay was not sufficiently specific and should not be generally used.

Response: Noridian concurs.